

PSJ3

Exhibit 214

INTERNET PHARMACY DATA

Meeting With
H. D. Smith
DEA Headquarters
January 4, 2006

Internet Pharmacies

- Domestic Based
 - Related to an existing pharmacy
 - Walk in patients with prescriptions
 - Some legitimate some not
 - Unrelated to brick and mortar pharmacy
 - No local patients or doctors
 - No walk-in business
- Foreign based

Domestic Internet Pharmacies are often part of an existing retail pharmacy so that some of the business is Internet and some is traditional retail pharmacy. Some of the business is legitimate and some is not.

Many domestic Internet pharmacies are separate from traditional retail pharmacies, with no walk-in business, no local patients or local doctors. Some of these types of operations are legitimate and some are not.

The foreign based Internet pharmacies that send controlled substances into the US are illegal. To import a controlled substance into the US, a DEA registered Importer would need to be involved to legally import controlled substances into the US.

Involved With Internet Pharmacies

- Doctors
- Pharmacies
- Distributors

- Internet Service Providers
- Credit Card Companies
- Delivery Services
- Internet Pharmacy Facilitators

ISSUES TO CONSIDER

- Frequency of Orders
- Size of Orders
- Range of Products Purchased
- Payment Method
- Pharmacy Location
- % Controlled vs. % Non-Controlled
- Customer pick up at distributor

When distributing controlled substances, distributors should consider these factors. They apply to all distributions, not only Internet pharmacies. Range, are they ordering a wide variety of drug products or only a few drugs. Payment method, does the customer have established credit and an established business? Location, is the pharmacy located in a location easy for customers or an industrial park? Is the pharmacy ordering 90% controlled substances or 10% controlled substances? Does the customer want to pick up orders for several pharmacies at the distributor?

DEA DISTRIBUTOR REGISTRATIONS

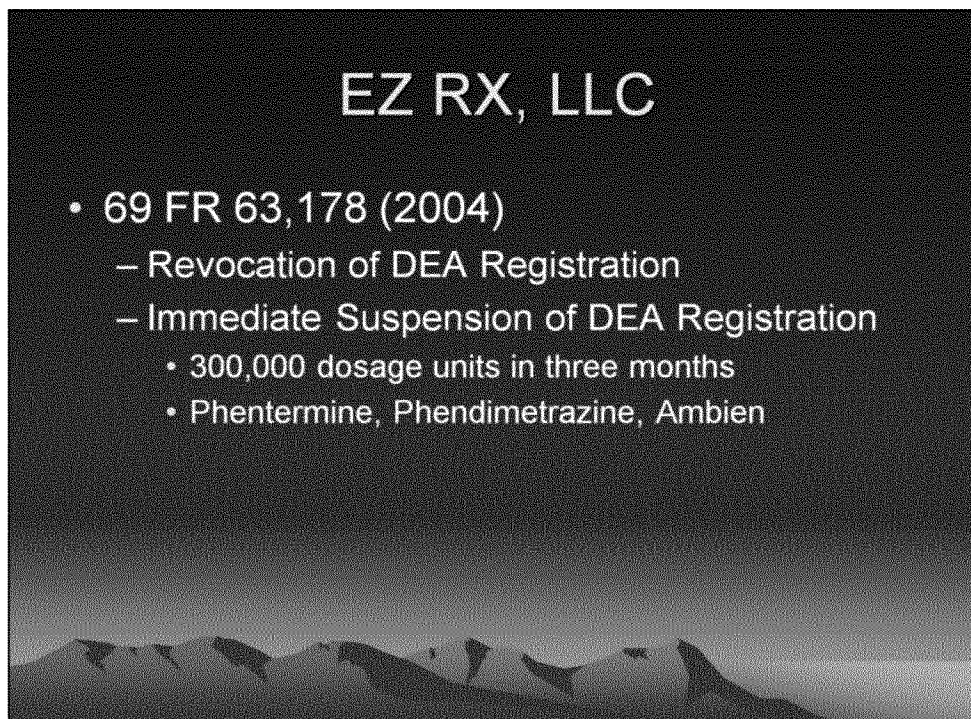
- Title 21 United States Code, Section 823
 - Is the registration in the public interest?
 - Maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical channels

When considering if a registration for a distributor of controlled substances is legitimate, we must consider if the distributor maintains effective controls against diversion of controlled substances

Supreme Court Case

- Direct Sales Co, Inc. v. United States (1943)
 - Mail order sales to doctor
 - Most sales were Morphine
 - Increase in quantities purchased
 - Business practices attracted customers who were violating the law
 - Drugs have inherent susceptibility to harmful and illegal use

This Supreme Court case was in 1943, many of the issues discussed in this case are relevant today and related to Internet cases.



The issues from 1943 relate to the Internet cases of 2004. The method of communication is different, but the result is the same.

RX Network of South Florida, LLC

- 69 FR 62,093 (2004)
 - Revocation of DEA Registration
 - Immediate Suspension of DEA Registration
 - 19,300,000 dosage units of various controlled substances
 - Based on Internet Questionnaires
 - Not in the course of professional practice

Supreme Court Case

- United States v. Moore
423 U.S. 122 (1975)
 - Usual course of professional practice
 - Patient with a Medical Complaint
 - History
 - Physical Examination
 - Nexus Between Complaint/History/Exam and Drug Prescribed

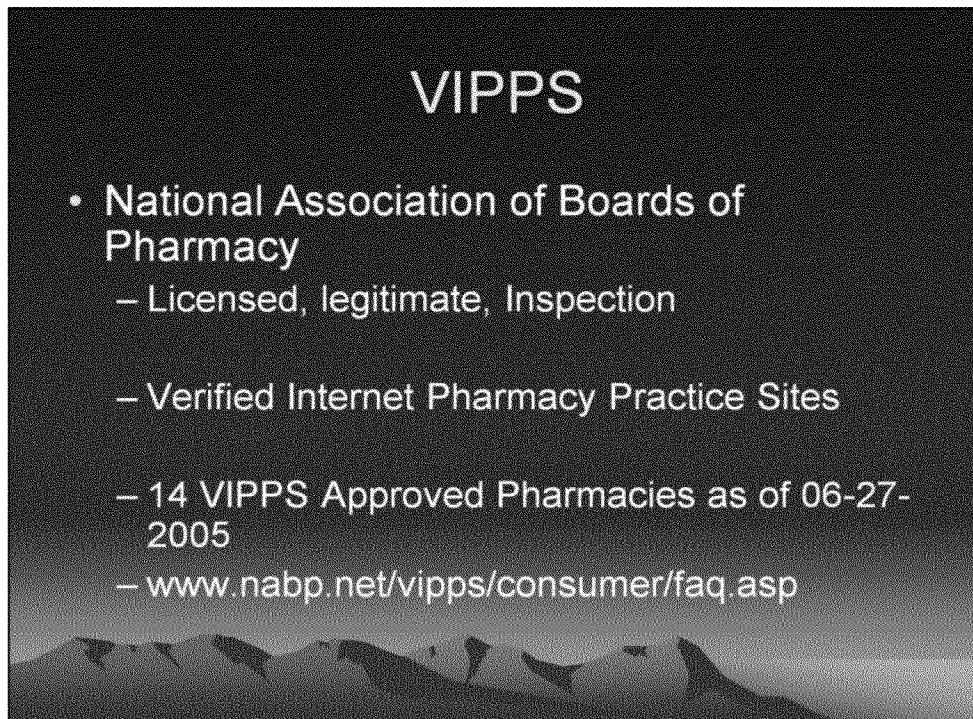
The United States V. Moore the supreme court held that, “Implicit in the registration of a physician is the understanding that he is authorized only to act ‘as a physician’.” “Acting as a physician is acting in the usual course of professional practice”

DEA Internet Policy

- 66 FR 21,181 (2001)
- Prescriptions can only be issued by a doctor acting in the usual course of professional practice
- Prescription not issued in the usual course of professional practice is not valid
- An Internet questionnaire alone is not sufficient to legally prescribe controlled substances

DEA issued a policy statement to registrants, law enforcement and regulatory authorities, and the public on April 27, 2001.

[D]



The National Association of Boards of Pharmacy initiated a program to certify Internet pharmacies that are properly licensed, follow the appropriate procedures, and are inspected by NAPB. Those sites have a VIPPS seal on the site, and by clicking on the seal you are linked to the NABP site to verify the legitimacy of the seal.

[D]

American Medical Association

- H-120.949 Guidance for Physicians on Internet Prescribing
 - valid patient-physician relationship, includes, but not limited to:
 - History and physical exam
 - Dialogue with patient
 - Follow up to assess outcome
 - Maintain medical record
 - Include electronic prescription in patient's medical record

The AMA has issued guidance for physicians to define legitimate Internet prescribing.

[D]

Federation of State Medical Boards

- Created Model Guidelines for the Appropriate use of the Internet in Medical Purpose
 - Treatment and consultation made in an online setting will be held to same standard as face-to-face settings.
 - Treatment based solely on an online questionnaire is not acceptable

[D]

Suspicious Orders

- 21 CFR 1301.74
- Requires that registrants design and operate system to identify suspicious orders
- Report suspicious orders to DEA when discovered

Suspicious orders VS. excessive purchases. Orders are before sales.

[D]

Suspicious Orders

- Reporting a suspicious order to DEA does NOT relieve the distributor of the responsibility to maintain effective controls against diversion

VERY important concept.

[D]

Suspicious Orders

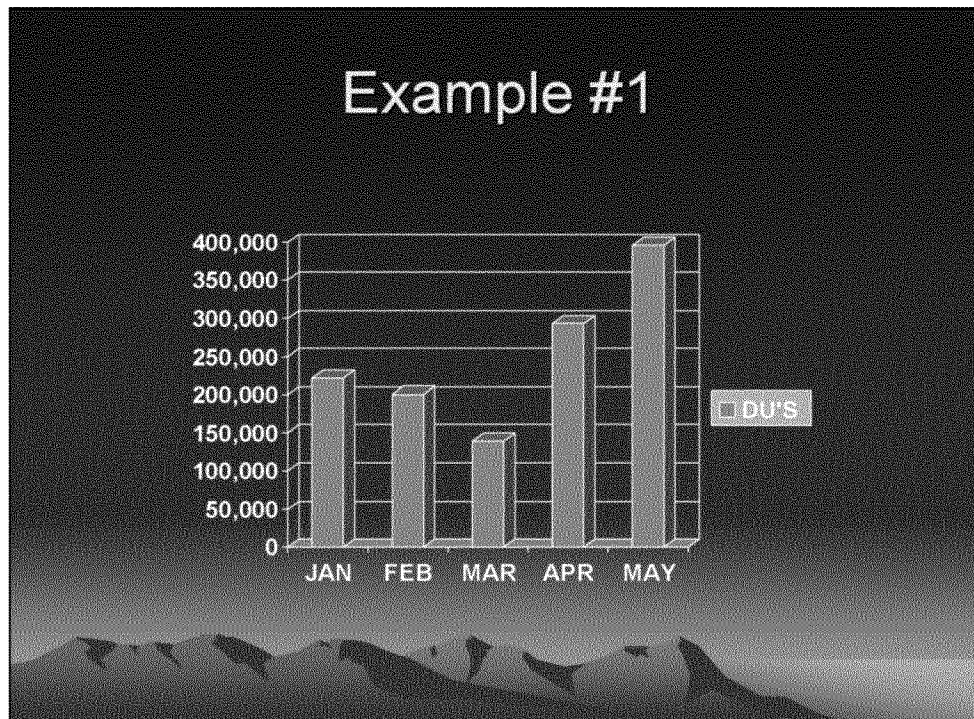
- DEA cannot tell a distributor if an order is legitimate or not
- Distributor must determine which orders are suspicious and make a sales decision

[D]

Example #1

- Retail pharmacy
 - Quantities of drugs
 - Range of drugs sold – only Phentermine
 - % controlled and % non-controlled
 - Size of orders over time
 - Location of store

[D]



[D]

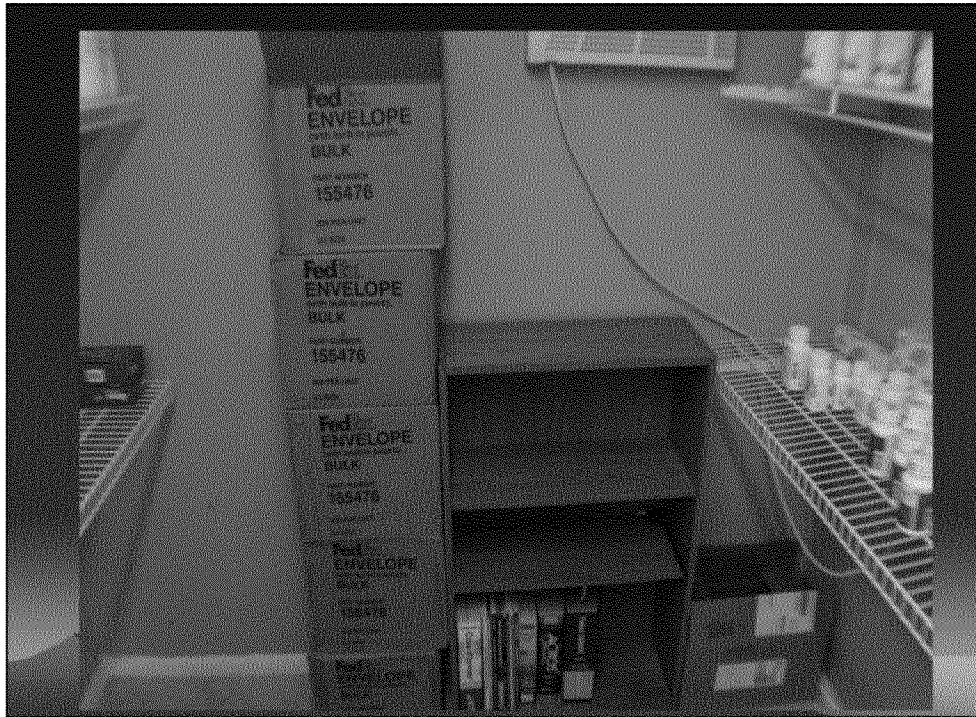
Example #2

- Retail Pharmacy
 - Location of store
 - Only Hydrocodone and Alprazolam
 - Very large quantities
 - FedEx boxes for delivery

ANOTHER PHARMACY



[D]

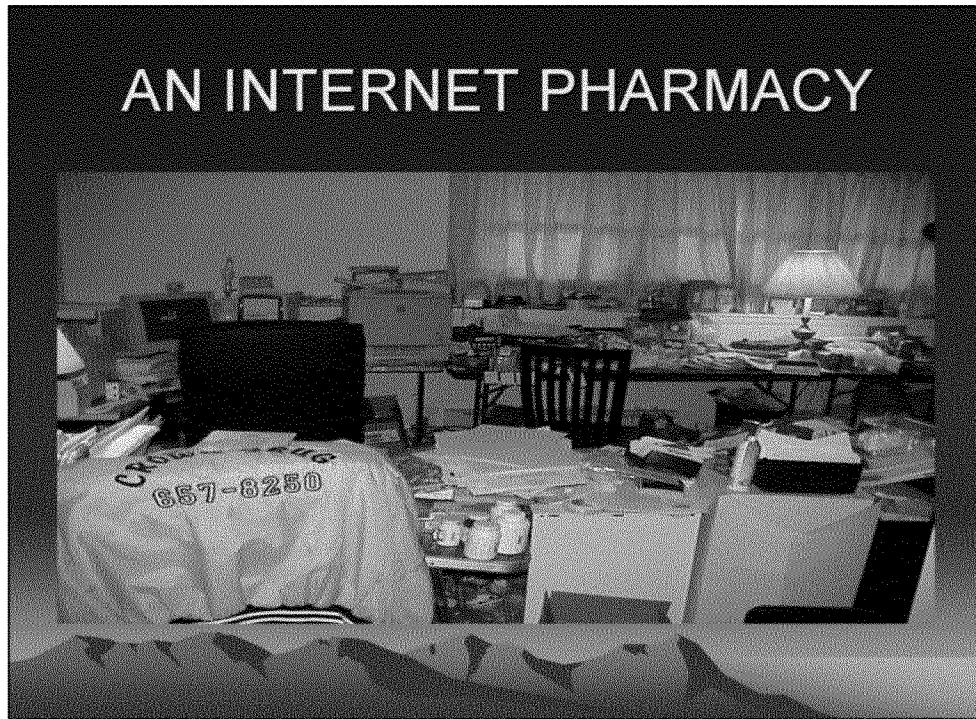


[D]

Example #3

- Advised Distributor they are an Internet Pharmacy
- No VIPPS approval
- Frequent Large Orders
- Hydrocodone and Benzodiazepines
- 99% controlled substances
- No established business credit

[D]



[D]

SUMMARY

- Prescriptions not written in the usual course of professional practice are not valid
- Drugs dispensed pursuant to invalid prescriptions are not for legitimate medical purpose, the drugs are diverted
- Not limited to Internet pharmacies

[D]

SUMMARY

- A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor
- The DEA registration of the distributor could be revoked under public interest grounds

[D]

SUMMARY

- Any Distributor who is selling controlled substances that are being dispensed outside the course of professional practice must stop immediately
- DEA cannot guarantee that past failure to maintain effective controls against diversion will not result in action against a distributor

[D]

SUMMARY

- DEA will:
 - Meet with other distributors involved in distributing to Internet pharmacies
 - Provide this information to your employees at your request
 - Meet with Industry groups or associations to discuss issue if requested

[D]

Contact Information

Michael Mapes

Chief, E-Commerce Section

703-653-2048

Kyle Wright

Chief, E-Commerce Operations Unit

703-653-2103

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